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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/576,841

04/20/2006

Harry Leneau

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ICE MILLER LLP

ONE AMERICAN SQUARE, SUITE 3100

INDIANAPOLIS, IN 46282-0200

EXAMINER

WARE, DEBORAH K

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/576,841	Applicant(s) LENEAU ET AL.	
	Examiner DEBBIE K. WARE	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 12-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 12-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-9 and 12-22 are presented for reconsideration on the merits.

Response to Amendment

The amendment filed April 26, 2010, has been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 and 12-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The process steps of lowering a temperature of the filtered colostrum so that the filtered colostrum is frozen or highly refrigerated, and sterilizing the filtered colostrum at the lower temperature are not supported by the original disclosure at the time the claimed invention was made. Furthermore, the lowering of the temperature to minimize denaturation and sterilizing the colostrum without centrifugation are not supported by the original disclosure.

This is a new matter rejection. These features newly claimed are, therefore, new matter. Without proper support by the original disclosure Applicants can not add new

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subject matter to the disclosure unless a CIP (continuation in part) is filed. The rejection is proper for consideration of the newly added claimed language of which there is not original support in the Application as filed by Applicants on April 20, 2006. No support could be found in the PCT or the provisional either, however, the instant application should be a duplicate copy of these cases. The amendment as presented on April 6, 2010, has introduced new matter, however, if Applicants can substantiate support for these amendments they are invited to point the Examiner at page number and line numbers wherein original support can be found. No support was noted at paragraph [0008] by the Examiner for the language as described above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 9, 12-16, 18, 20 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by **newly cited** Cockrum (USP 5645834), cited on enclosed PTO-892 Form.

Claims are drawn to a composition and method for preparing sterile bovine colostrum by filtering a bovine colostrum to remove large components while retaining antibodies, lowering a temperature of the filtered colostrum so that the filtered colostrum is frozen or highly refrigerated, and sterilizing the filtered colostrum at the lower temperature.

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Cockrum teaches a composition and method for preparing sterile bovine colostrum by filtering a bovine colostrum to remove large components while retaining antibodies, lowering a temperature of the filtered colostrum so that the filtered colostrum is frozen or highly refrigerated, and sterilizing the filtered colostrum at the lower temperature. The colostrum is injectable into a juvenile cow, a calf, and can be performed subcutaneously, note col. 3, lines 30-55 and see the abstract and col. 12, lines 5-35. Also see col. 17, lines 10-50. The sterilizing is carried out in the absence of centrifugation because there is no disclosure of centrifugation. Since the sterilizing is carried out at a lower temperature, minimal denaturation is inherent to the disclosed step and temperature disclosed by Cockrum. The colostrum is obtained from the same species, a warm blooded bovine animal.

The claims are identical to the cited disclosure and are, therefore, considered to be anticipated by the teachings therein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-8, 17, 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cockrum, as cited above, in view of previously cited WO 97/16977 (WO) and Hies et al (USP 5147548).

Claims are further drawn to filtering raw colostrum and sterilizing using gamma irradiation, filtering using a series of filters (10, 5 and 3 micron filters), and a second dose can be administered to the animal.

Claims differ from Cockrum in that these claim features are not disclosed specifically.

WO teaches WO teaches a composition and method of preparing a sterile bovine colostrum that has been highly filtered by filtering (e.g. ultrafiltration) colostrum to remove large components while retaining antibodies, sterilizing the colostrum and providing in liquid form. Note abstract and page 4, lines 4-9 and lines 23-31. Raw colostrum is disclosed.

Hies teaches Hies et al teach a sterilized colostrum, method of producing it and providing it to a bovine, see entire document and the abstract, all lines. Also note that that steps of filtering and sterilizing are disclosed, see column 3, lines 26-28, wherein

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the filter size is 5 micron, and a series of filters is disclosed. Also at column 1, lines 40, gamma radiation treatment is disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to carry out the process steps of Cockrum on raw colostrum as disclosed by WO and to further sterilize the colostrum using a series of filters of small micron size (e.g. 5 microns) and gamma irradiation as disclosed by Hies et al. To select a second dose for later use is clearly within the purview of an ordinary artisan especially since the colostrum is frozen and storable in this state, as disclosed by the cited prior art. Clearly one of skill in the art would have expected successful results for modifying filter size around 5 microns as disclosed by Hies et al because filtering is well known to cause denaturing of the proteins.

Thus, filtering using a the colostrum at a lower temperature would have had the expected result of minimal denaturization because the colostrum is frozen and in a protected state. Also the filter sizes of 10, 5, and 3 micron would have been expected to provide a purified and sterile colostrum ready to be injected into a warm blooded juvenile calf. Hence each of the claimed features are disclosed and one of skill would have been motivated to carry out these steps with the expectation of successful results because the art teachings the success of these steps and the art also recognizes that colostrum can be sterilized using gamma irradiation with the predicted and expected successful result of resulting sterilized colostrum product that is injectable subcutaneously. The claims are prima facie obvious over the cited prior art.

Response to Arguments

Applicant's arguments filed April 2, 2010, have been fully considered and are persuasive because of the amendments presented. However, based on the newly amended claims a new updated search was conducted which revealed better art to apply over the claims as noted above. These are new rejections based upon Applicants' amendments.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBBIE K. WARE whose telephone number is (571)272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah K. Ware/

Deborah K. Ware

Primary Examiner

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